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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------|------------------|
| 09/973,853   | 10/10/2001  | Neville J. Anthony   | 20757Y                | 7109             |
| 210  | 7590        | 04/01/2004           | EXAMINER              |                  |
| MERCK AND CO INC<br>P O BOX 2000<br>RAHWAY, NJ 070650907 |             |                      | COLEMAN, BRENDA LIBBY |                  |
|  |             |                      | ART UNIT              | PAPER NUMBER     |
|  |             |                      | 1624                  |                  |

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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## Office Action Summary

Application No.

09/973,853

Applicant(s)

ANTHONY ET AL.

Examiner

Brenda L. Coleman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-37 is/are pending in the application.
- 4a) Of the above claim(s) 16-20, 28, 29 and 33-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-15, 21-27, 30-32 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 1 and 3-37 are pending in the application.

This action is in response to applicant's amendment filed January 9, 2004.

Claims 1, 4, 5, 7-9, 11, 21-24, 27 and 31 have been amended.

### ***Election/Restrictions***

1. Claims 16-20, 28, 29 and 33-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13.

### ***Response to Amendment***

Applicant's amendments and arguments filed January 9, 2004 have been fully considered with the following effect:

2. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 25-27 and 30-32, the applicant's amendments and remarks have been fully considered but they are not persuasive. The applicants stated that "the specification provides a description sufficient to enable one of ordinary skill in the art to use the entire scope of the invention set forth in the claims without undue" and that "HIV integrase inhibitors and that the compounds are useful for inhibiting HIV integrase, for treating HIV infection, for treating AIDS and for delaying the onset of AIDS". HIV integrase inhibitors may not necessarily be the mode of action of the compounds, which are tested. Pommier et al., Antiviral Research exhibits many compounds which are suspected of being HIV-1 integrase inhibitors in Table 4 on page 145. However, is integrase really the target. As pointed

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out by Pommier, diketo acids are the only compounds found to selectively target integrase. Erik De Clercq also stated in 2002 that "the problem with integrase inhibitors is that while they might be effective in an enzyme-based assay, their anti-HIV activity in cell culture may be masked by cytotoxicity, and if they do exhibit anti-HIV activity, this could, at least in some cases be attributed to antiviral actions targeted at other steps in the HIV replicative cycle".

Where the utility is unusual or difficult to treat or speculative, the examiner has authority to require evidence that tests relied upon are reasonably predictive of in vivo efficacy by those skilled in the art. See *In re Ruskin*, 148 USPQ 221; *Ex parte Jovanovics*, 211 USPQ 907; MPEP 2164.05(a).

Patent Protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. Tossing out the mere germ of an idea does not constitute enabling disclosure. *Genentech Inc. v. Novo Nordisk* 42 USPQ2d 1001.

Claims 25-27 and 30-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

3. The applicant's amendments are sufficient to overcome the 35 USC § 112, second paragraph rejections labeled paragraph 3a-ac) of the last office action which are hereby **withdrawn**.

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4. The applicant's arguments are sufficient to overcome the obviousness-type double patenting rejection labeled paragraph 4) of the last office action which is hereby **withdrawn**.

5. With regards to the provisional obviousness-type double patenting rejection as being unpatentable over copending Application No. 10/399,083, Attorney Docket No. 20950Y, 10/398,929 and 10/218,537 of the last office action, the applicant's remarks have been fully considered but they are not persuasive. The applicant's stated that when the only rejection remaining is a provisional double patenting rejection, the Examiner should withdraw the rejection and allow the application to issue as a patent. However, this is not the only issue remaining.

Claims 1, 3-15, 21-27, 30-32 and 37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/399,083, for reasons of record and stated above.

6. Claims 1, 3-15, 21-27, 30-32 and 37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. (Attorney Docket No. 20950Y), for reasons of record and stated above.

7. Claims 1, 3-15, 21-27, 30-32 and 37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

claims of copending Application No. 10/398,929, for reasons of record and stated above.

8. Claims 1, 3-15, 21-27, 30-32 and 37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/218,537, for reasons of record and stated above.

9. In view of the amendments to the claims of copending Application No. 10/398,988 the rejection of claims 1, 3-15, 21-27, 30-32 and 37 under the judicially created doctrine of obviousness-type double patenting is hereby **withdrawn**.

In view of the amendment dated January 9, 2004, the following new grounds of rejection apply:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1, 3-13, 25-27 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The applicants

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amendment to the definition of the substituents on  $R^k$ , where  $R^k$  is substituted by –  $N(R^a)R^t$  and  $R^a$  is hydrogen or  $C_{1-6}$  haloalkyl is not defined in the specification.

Applicant is required to cancel the new matter in the reply to this Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

11. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a) Claim 11 recites the limitation " $-N(R^a)-C(=O)-(CH_2)_{1-2}-C(=O)-N(R^a)_2$ " in the definition of the substituents on  $R^k$ . There is insufficient antecedent basis for this limitation in the claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00 Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Brenda Coleman  
Primary Examiner Art Unit 1624  
March 30, 2004